

Translation

Rec'd PCT/PTO 01 JUN 2005
PCT/DE2003/003950

PATENT COOPERATION TREATY

PCT

10/537181

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference J50005PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/DE2003/003950	International filing date (day/month/year) 01 December 2003 (01.12.2003)	Priority date (day/month/year) 02 December 2002 (02.12.2002)
International Patent Classification (IPC) or national classification and IPC G01J 3/46		
Applicant JOHANN WOLFGANG GOETHE-UNIVERSITÄT FRANKFURT AM MAIN		

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 12 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☒ (sent to the applicant and to the International Bureau) a total of 4 sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

Date of submission of the demand 01 July 2004 (01.07.2004)	Date of completion of this report 07 February 2005 (07.02.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

☐ The international application as originally filed/furnished

☒ the description:

pages _____ 1-12 _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ 1-16 _____ received by this Authority on 13 January 2005 (13.01.2005)

pages* _____ received by this Authority on _____

☒ the drawings:

pages _____ 1/1 _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (specify): _____

☐ any table(s) related to sequence listing (specify): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (specify): _____

☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☒ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

☒ all parts.

☐ the parts relating to claims Nos. _____

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of IV.3

See Supplemental Sheet

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	8-10, 13-16	YES
	Claims	1-7, 11, 12	NO
Inventive step (IS)	Claims		YES
	Claims	1-16	NO
Industrial applicability (IA)	Claims	1-16	YES
	Claims		NO

2. Citations and explanations

See Supplemental Sheet

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Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

1. Citations

- D1: US-A-6 006 119 (MICHEELS RONALD H ET AL.)
21 December 1999 (1999-12-21)
- D2: WO 01/69302 A (CHEN SHIPING; GENOSPECTRA INC
(US)) 20 September 2001 (2001-09-20)
- D3: DE 41 05 493 A (HELMUT WINDAUS LABORBEDARF UND)
27 August 1992 (1992-08-27)
- D4: US 2002/018209 A1 (LOUDERMILK ALAN R ET AL.)
14 February 2002 (2002-02-14)
- D5: US-A-4 329 190 (BERG HOWARD M ET AL.) 11 May
1982 (1982-05-11)
- D6: EP-A-0 987 769 (SUMITOMO ELECTRIC INDUSTRIES)
22 March 2000 (2000-03-22)
- D7: EP-A-1 154 298 (CIT ALCATEL) 14 November 2001
(2001-11-14)
- D8: US-A-6 151 107 (EBERHARD PATRICK ET AL.)
21 November 2000 (2000-11-21)
- D9: US-A-5 313 941 (GOLDBERGER DANIEL S ET AL.)
24 May 1994 (1994-05-24)
- D10: US-B1-6 334 065 (KIANI MASSI E ET AL.)
25 December 2001 (2001-12-25)
- D11: US-A-6 049 727 (CROTHALL KATHERINE D)
11 April 2000 (2000-04-11)
- D12: US-A-6 157 454 (EMERSON GARY ET AL.)
5 December 2000 (2000-12-05)
- D13: EP-A-1 260 877 (XEROX CORP) 27 November 2002
(2002-11-27)
- D14: US 2002/045808 A1 (TIERNEY MICHAEL J ET AL.)
18 April 2002 (2002-04-18)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

re Box IV:

2. The present application does not meet the **requirement of unity of invention** (PCT Rule 13), since the subject matter of independent claims 1 and 2, namely a transmission spectrometer and a reflection spectrometer respectively, having a plurality of radiation sources, the intensity of which is variable and which together have a broadband emission spectrum, is known from D1 (cf. point 3). Furthermore, the dependent claims are directed to the solution of different problems.

2.1 In detail:

Claims 1-7, 11, 12, 15, 16 are directed to the problem of providing a spectrometer permitting the measurement of photometric variables in different spectral ranges. This problem is solved by the use of light sources which emit in different spectral ranges.

Claims 8-10, 13, 14 are directed to the problem of providing signal analysis that permits the determination both of parameters that do not vary over time and of parameters that vary over time. The claims propose that, for this purpose, individual spectra are recorded at intervals of microseconds to seconds and that the signal is separated into a component that is constant over time and a component that

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Continuation of:

varies over time.

It is clear from the different problems mentioned and their distinctive solutions that the above-identified groups of claims do not have any common or corresponding technical features whereby the claims are so linked as to form a single inventive concept (PCT Rule 13.1 and 13.2).

- 2.2 The applicant has paid additional examination fees. The examination is therefore carried out for the following groups of claims:

Group 1: Claims 1-7, 11, 12, 15, 16

Group 2: Claims 8-10, 13, 14

re Box V:

Group 1: Claims 1-7, 11, 12, 15, 16

3. The present application does not satisfy the criteria of PCT Article 33(2) because the subject matter of the present **claim 1** is **not novel**.

- 3.1 First, it should be noted that the feature "**especially** via the power supply to the radiation sources" is merely an option and does not therefore limit the scope of the claim.

- 3.2 Furthermore, D1 discloses (cf. fig. 12A-C, column 18, lines 11-50):

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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

- A transmission spectrometer having a probe 790,
- to which probe there can be supplied, via at least one radiation emission conductor 750', radiation from at least one radiation source 704 for the purpose of being directed onto and/or into an object for examination 705', and
- having at least one radiation receiving conductor 790' which is spaced apart from the probe and via which there can be supplied to a radiation receiver 710, which can be connected to an analysis unit 670, radiation, especially fluorescent radiation, that is diffused, transmitted and/or emitted on and/or in the object for examination, wherein
- there is provided a plurality of radiation sources 704,
- the radiation intensities of which are all variable (column 17, lines 52-65),
- which have an emission spectrum which is broadband either for each radiation source or for all the radiation sources (column 17, lines 22-24), and
- each of which is directly coupled to a radiation emission conductor (fig. 12B, column 18, lines 18-19),
- the radiation receiver receives the whole spectrum of the radiation which enters the radiation receiving conductor by diffuse and/or specular reflection, passage, emission and/or fluorescence (since only one detector is used, said detector must implicitly receive the whole spectrum if it is to be able to measure transmission over

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Continuation of:

the whole spectrum), and

- in the analysis unit at least the intensity of a defined wavelength can be processed according to at least one program which is selectable via an operator's station for the calculation of at least one parameter (calculation of the haematocrit content of the sample, cf. column 2, lines 32-45), and in which the analysis unit is functionally connected to the radiation sources in such a way that, according to the program selected, the intensity of the radiation emitted by each radiation source is individually variable (cf. column 14, lines 10-19, according to which the LEDs are individually controlled with a square wave, sine wave or pulse modulated signal; according to lines 37-40 this control function can alternatively be performed by an external computer which also separates the different signals and can therefore be regarded as an analysis unit).

D1 therefore discloses a spectrometer with all the features of the present claim 1.

- 3.3 The subject matter of claim 1 is also **found to lack novelty** over the disclosure in D11 (cf. fig. 1 and 2; and column 7, line 52 to column 9, line 27), which likewise discloses a spectrometer having a plurality of light sources, the radiation of which is conveyed to the sample via a radiation emission conductor 34, and also having a radiation receiving conductor 42, which conveys radiation from the

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

sample to the detector. D11 also discloses that the intensity of the light sources can be individually controlled (cf. column 9, lines 12-27).

- 3.4 The subject matter of the present independent **claim 2** also lacks novelty (PCT Article 33(2)) for the following reasons:

Amended **claim 2** now contains the following features which were not included in the claim as originally filed:

- (a) the radiation incoupling end of the radiation receiving conductor is surrounded by the radiation outcoupling ends of the radiation emission conductors, preferably in a substantially annular manner, such that the apertures of the radiation emission conductor and of the radiation receiving conductor overlap in the measurement region,
- (b) the analysis unit is functionally connected to the radiation sources in such a way that, according to the program selected, the intensity of the radiation emitted by each radiation source is individually variable.

First, it is unclear how the radiation receiving conductor can be "**surrounded**" by the "at least one radiation emission conductor" defined by claim 2.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Consequently, the word "surrounded" can be construed only as meaning "arranged".

Second, it should be noted that the feature "**preferably** in a substantially annular manner" is merely an option and does not therefore limit the scope of the claim.

D1 discloses in fig. 12A and in column 18, lines 9-49, a reflection spectrometer having the features defined in **claim 2** as originally filed (cf. also point 3.2), that is to say, a spectrometer having a radiation receiving conductor that is not necessarily spaced apart from the probe and that detects reflected instead of transmitted radiation.

The radiation emission conductors and the radiation receiving conductors are also implicitly arranged in such a way that their apertures overlap in the measurement region, since otherwise it would be impossible to absorb the light reflected on the sample with the radiation receiving conductors, which is the fundamental purpose of the arrangement shown in fig. 12.

D1 also discloses feature (b) of amended claim 2 (cf. point 3.2).

D1 therefore discloses a spectrometer with all the features of the present claim 2.

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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

3.5 It should also be noted that even a clarified claim indicating that the reflection spectrometer has a plurality of radiation emission conductors, the outcoupling ends of which surround the incoupling end of the radiation receiving conductor in an annular manner, would not be considered inventive (PCT Article 33(3)). Although D1 shows in fig. 12A an arrangement in which the radiation emission conductors are surrounded by the radiation receiving conductors, D1 proposes alternatively in fig. 10B and fig. 14 arrangements in which, conversely, the radiation receiving conductor is surrounded by the radiation emission conductors. A person skilled in the art looking for an alternative to the arrangement of radiation conductors as shown in fig. 12A would not therefore hesitate to use an arrangement of radiation conductors as shown in figure 10B or figure 14 if circumstances so dictated, and he would not thereby have to be inventive.

3.6 It should, moreover, be noted that **claim 2** could be **found to lack an inventive step** (PCT Article 33(3)) also on the basis of D2, which likewise discloses a spectrometer having a plurality of radiation sources, the radiation intensity of which is variable, and the radiation of which is conveyed to the sample via optical fibres, the apertures of the radiation emission conductor and of the radiation receiving conductor again having to overlap.

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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Furthermore, the radiation emitted by the sample is supplied to a detector via a further fibre (cf. fig. 1 and 6; and page 13, line 14 to page 14, line 30). For a person skilled in the art, the teaching of D1 or D11 suggests the individual control of the output generated by the diodes.

- 3.7 Dependent claims 3-7, 11, 12, 15, 16 do not contain any features which in combination with the features of any claim to which they refer back satisfy the PCT novelty and inventive step requirements. The reasons are as follows:

Claims 3-6: spectrometers having a red, blue and green light source are generally known (cf., for example, D1, which proposes covering the spectral range of 400-2000 nm and where the bandwidth for each LED in the embodiment is 30-100 nm, or D3, which explicitly proposes a red, a green and a blue LED, cf. column 4, lines 35-39). Consequently a person skilled in the art is also familiar with the use of LEDs which emit in not entirely overlapping spectral ranges with different intensity.

Claim 7: The use of a diode array in the radiation receiver is known from D1 (cf. fig. 14A).

Claims 11, 12: a spectrometer which is designed for the measurement of haemoglobin concentration, the analysis unit of which spectrometer is functionally connected to the radiation sources in such a way

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(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

that the intensity of each radiation source is variable, and where the probe can be handheld, is known from D1.

Claims 15 and 16 merely define the common range of applications for transmission spectrometers and reflection spectrometers.

Group 2: Claims 8-10, 13, 14

4. The subject matter defined by **claims 8 and 10 or 13** does not satisfy the criteria of PCT Article 33(3), since it **does not involve an inventive step** for the following reasons:

4.1 As already stated under **point 3**, the subject matter of claims 1 and 2, to which claims 8, 10 and 13 refer, is already disclosed by D1 and D11.

4.2 **Claims 8, 10 and 13** are directed to the problem of providing specific signal analysis in the spectrometers and define specific characteristics of the signal analysis.

4.3 The apparatus known from D11 in particular is a spectrometer for the determination of constituents such as glucose in body fluids such as blood. Although D11 itself describes a signal analysis unit, a person skilled in the art wishing to improve the efficiency of the D11 apparatus would be induced to consider alternative signal

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

processing methods. In his search for these, the skilled person would find, for example, D9, which proposes that the detection signal be sampled at time intervals of 0.1-2 msec and be analysed, for example, for distinctive features of the signal in order to synchronise the measured signal with the systolic and diastolic phases of the heart beat (cf. column 5, lines 41-51; and column 7, line 30 to column 8, line 17). A person skilled in the art implementing an analysis method of this kind then, however, arrives in an obvious manner at subject matter having all the features of claim 15.

The subject matter of **claim 9**, which is dependent on claim 8, is therefore likewise suggested.

- 4.4 The D11 spectrometer is generally intended for the determination of body fluid constituents. Apart from the determination of glucose, the determination of oxygen saturation is a generally known field in which spectrometers are successfully used (cf. D11, column 2, lines 3-5). A person skilled in the art wishing to adapt the spectrometer for this range of applications will find appropriate instructions in, for example, D8, which proposes a method for the determination of blood oxygen saturation. In particular, D8 proposes the separate detection of the steady components (DC) and time-dependent components (AC) of the signal measured in transmission (cf. column 2, lines 35-41). A person skilled in the art using the

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

measurement method proposed in D8 in the D11 apparatus will, however, automatically arrive at apparatus having all the features of claim 10.

- 4.5 A person skilled in the art will find an alternative method of operating a transmission spectrometer for the determination of blood oxygen saturation in D10. Said document proposes modulating two light sources, which emit in different spectral ranges, in such a way that only one of the two light sources is emitting at a given time. The single detector used then picks up a time-division multiplexed signal. A person skilled in the art using the measurement method proposed in D10 in the D11 apparatus will, however, automatically arrive at apparatus having all the features of claim 13.

The subject matter of claim 14 is therefore likewise suggested.